Table 1

MRA in the Diagnosis of Hemodynamically Significant Artery Stenosis

I. Renal Arteries

Author /Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
Bongers V 2000	P, B, Consecutive Inclusion criteria: Pts with clinical suspicion of RAS Exclusion criteria: MRI contraindications All pts had captopril renography (CR) & MRA within 6 weeks before DSA Renogram read by 2 nuclear medicine MDs in consensus who were not aware of MRA or DSA results DSA read by 2 additional radiologists who did not perform the DSA, nor were they aware of CR or MRA results MRA read by 2 radiologists in consensus, prior to performing DSA. Neither were aware of renogram result	43 pts, 121 arts 57yrs(21-40) 23♀, 20 ♂	3D CE-MRA vs. DSA	100 %	94%	The sens/spec in this table reflects comparative results of MRA vs. DSA only Out of 19 accessory arteries found by DSA, MRA missed 2

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Chan et al, 2001	P A single radiologist independently compared all patients to DSA within 5 wks of the CE-MRA	17 pts 17 arts 41yrs (34-64) 6♀, 11 ♂ Out of a pool of 196 f/u renal transplant recipients, 17 were recruited for systolic bruit in the transplant region 18.8 mo (2-86.3 mo) after transplant	3D CE-MRA vs. DSA	100%- iliac artery 100%- Anastomosis 100%- graft renal artery	100%- iliac artery 83%- Anastomosis 100%- graft renal artery	Uncertain whether the assessors were masked The sensitivity and specificity varied depending on the area of assessment 2 FP of >50% stenosis by MRA. 1 pt due to marked turbulence from sharp kinking of transplant artery.
De Cobelli et al, 1996	P, B, consecutive Pts screened for hypertension and other factors using criteria described 28/50 pts had confirmatory exam using DSA as reference standard. DSA performed within 1 week of MRA. MRA analyzed by 2 radiologists in consensus, who were masked DSA findings	50 pts, 101 arts 53 yrs (16-83) 27♀, 23 ♂ All pts were suspected to have renocardiovascular disease	3D CE-MRA vs. DSA	90%	99%	MRA detected 101 of the 103 arteries detected by DSA. The missed arteries were 1 accessory artery outside the imaging volume, and 1 artery with a stent Not all 50 pts received a DSA, and no explanation was given 1 FP, 2 FN (1 severe proximal stenosis was depicted as mild and 1 distal stenosis not seen on MRA was sue to fibromuscular dysplasia.)

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De Cobelli et al, 2000	P, B DSA was conducted within 2 wks of the MRA and US and read by 1 vascular radiologist masked to results of MRA and US. 2 radiologists assessed results of MRA by consensus and were masked to results of DSA 1 vascular radiologist assessed results of US	45 pts, 103 arts 58yrs (23-75) 22♀, 23 ♂ Pts referred for suspected RAS. Selected on basis of clinical criteria for moderate to high possibility of renovascular disease	Protocol evaluated combined 2D & 3D unenhanced MRA vs. Doppler ultrasonography vs. DSA	MRA: 100% US: 79% Both MRA & US had 100% sensitivity for totally occluded vessels	MRA: 93% US: 93% Both MRA and US had 100% specificity for totally occluded vessels	17 of 45 pts were enrolled in another study whose findings were published in DeCobelli et al, 1997 Depiction of 89 of 103 (86%) arteries possible through US Depiction of 102 of 103 (99%) arteries possible through MRA The MRA results reported were combined for both enhanced and unenhanced MRA MRA classified 2 normal arteries as severe stenoses and 3 mild stenoses as severe stenosis Because the assessors had to reach consensus the inter-rater reliability cannot be assessed

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De Haan et al, 1996	P, B One inclusion criteria was ability to conduct MRA 48 hours before DSA. or CA DSA was performed in cases where arteries were not clearly depicted 1 radiologist without knowledge of pts clinical background or MRA results, assessed results of CA or DSA 1 vascular radiologist and 1 MR radiologist who had no knowledge of the clinical background of pts evaluated results of all 3 MRA techniques individually	38 pts, 89 arts 60 yrs (37-78) - men 55 yrs (24-74) - women 24♀, 14 ♂ All pts had therapy-resistant hypertension and were referred for testing Most of the pts had undergone routine evaluation for renovascular hypertension	3D MRA with and without cardiac synchronization vs. CA or DSA (no contrast used)	100% with no gating 100% with diastolic gating 100% with systolic gating	96% with no gating 96% with diastolic gating 82% with systolic gating	Reference of CA or DSA was not consistent 3 pts were excluded (2 for claustrophobia and 1 for metal fragments in the back) Of 87 arteries, 82 were seen by MRA without gating, 83 by MRA with systolic gating, and 84 by one observer and 83 by the other for MRA with diastolic gating No significant difference between the 3 MRA techniques in the diagnosis of >50% stenosis

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Fain et al, 2001	P, B 180 pts with suspected RAS received MRA. Of these, the 25 pts in the study population then also underwent DSA. All 25 pts received DSA, and <u>small</u>-FOV MRA. Only 23/25 pts received DSA and <u>large</u>-FOV MRA. Assessors were masked to the results of the second MRA, but there was no mention of whether they knew the results of the previous MRA 2 MR angiographers reached consensus for each observation	25 pts, 55 arts 65yrs (8-83) 17♀, 8 ♂	Small-FOV 3D CE-MRA and large-FOV 3D CE-MRA vs. DSA	97%- high-spatial-resolution small-FOV 3D MRA 79%-large-FOV 3D MRA	92%-small-FOV 3D MRA 91%-large-FOV 3D MRA	Small-FOV depicted 9/10 accessory renal arteries and 45/45 main arteries Large-FOV depicted 8/10 accessory renal arteries and 41/41 main arteries Using small-FOV MRA, 2 cases of significant RAS were missed and 1 overestimated Using large-FOV MRA, 2 cases of significant RAS were missed and 6 overestimated. There was no explanation of why only 25 pts out of 180 were included in the study. Two pts did not receive large-FOV. One was technically unsuccessful. The other was not performed. No reason given. Because the assessors had to reach consensus the inter-rater reliability cannot be assessed

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Hahn et al, 1999	P, B MRA was conducted between 0-69 days (mean 6.6 days) after CA MRA assessed by 2 independent radiologists with no knowledge of CA results Results of CA and MRAs were graded by consensus observations	22 pts 67yrs (25-83) 7♀, 15 ♂ All patients had at least 1 RAS previously confirmed by CA	3D phase-contrast unenhanced MRA 3D phase-contrast CE-MRA 3D single breath-hold CE-MRA vs. catheter angiography	95% Unenhanced phase-contrast 3D MRA 85% phase-contrast 3D CE-MRA 91% single breath-hold 3D CE-MRA 100% for occluded vessels in all 3 MRA	38% Unenhanced phase-contrast 3D MRA 52% phase-contrast 3D CE-MRA 79% single breath-hold 3D CE- MRA 100% for occluded vessels in all 3 MRA	2 pts were excluded from analysis because of an incomplete MR examination due to claustrophobia Inter-rater reliability (0.62) was best for 3D single breath-hold CE-MRA for detection of significant stenosis Unenhanced phase-contrast 3D MRA failed to detect 8 accessory renal arteries Phase-contrast 3D CE-MRA failed to detect 8 accessory renal arteries Single breath-hold 3D CE-MRA failed to detect 3 accessory renal arteries

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Huber et al, 2001	P, B Indication for DSA after examination by MRA was allograft failure of the kidney or hypertension DSA assessed by 2 vascular radiologists reaching consensus and unaware of the MRA results MRA assessed by 2 MR radiologists separately then together who were unaware of the DSA results	41 pts 42yrs (+/-17.4yrs) All pts post-kidney transplantation with goal of assessing postoperative complications	3D CE-MRA vs. DSA	Radiologist #1 100% Radiologist #2 100% 100% - consensus	Radiologist #1 97% Radiologist #1 93% 100% - consensus	Inter-rater reliability was 0.92 for patient-based and 0.96 for segment-based analysis Radiologist #1 – 1 false positive overestimation of a mild stenosis in external iliac artery Radiologist #2 – 2 false positive overestimations of a mild stenosis in the renal artery and segment artery

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Korst et al, 2000	P, B DSA assessed by 2 radiologists who were unaware of the results of MRA MRA assessed by 2 radiologists who were unaware of DSA results Consensus was obtained for both DSA and MRA results	38 pts, 93 arts 54yrs (18-75) 25♀, 13 ♂ Pts suspected of having RAS	Enhanced 3D CE- MRA vs. DSA	100% 100% for totally occluded vessels	85% 100% for totally occluded vessels	MRA depicted 75 of 75 (100%) main arteries and 13 of 17 (76%) accessory arteries Inter-rater reliability was 0.90 for DSA and 0.91 for MRA No adverse reactions or complications occurred during DSA nor MRA 4 arteries were overestimated as having significant stenosis by MRA
Mittal TK 2001	P,B MRA performed prior to DSA in all but 1 pt. Both tests performed within 1 week of each other MRA performed and evaluated by a separate radiologist masked to results of DSA.	41 pts, 52 arts 30-85yr 24♀, 18♂ 26 pts w/ clinical suspicion of RAS 16 pts who were potential kidney donors (1 excluded for claustrophobia)	3D CE-MRA vs. DSA	95%	93%	MRA identified all 52 main arts and 7 accessory arts shown on DSA in patients with suspected RAS In kidney donors, MRA identified all 25 main renal arts without early branching seen on DSA, and 4 of 5 renal arts with early branching. The unidentified early branch on MRA led to the art being classified as the main renal artery. Breathing artifact was blamed for this error. MRA also correctly identified 4 accessory arts seen on DSA.

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Qanadli SD 2001	P,B 79 kidneys analyzed (2 inconclusive) MRA read by 2 radiologists, masked to results of other exams If there was >1 renal art, the most stenotic was considered. If there was >1 stenotic area, the most stenotic was considered Inclusion criteria: Pts with suspected RAS due to one or more of the following: Severe HTN, Refractory HTN despite optimal medical management, acceleration of HTN, abdominal or flank bruit The exclusion criteria were extensive, but were defined *a priori*	41 pts, 52 arts 64yrs(41-78) 15♀, 26♂ During study period, 107 patients initially approved, but 30 excluded for various reasons. Also, 36 refused to undergo all 4 examinations.	All 41 pts received Captopril Doppler, Captopril Scintigraphy, DSA & CE-MRA within 3 months	95%	82%	Vessels evaluated at 50% and 70% stenotic threshold Indeterminate Cap Dopp or Cap Scint results considered + as per usual clinical practice Compared to DSA, CE-MRA tended to overestimate degree of stenosis. Among 41 kidneys with >50% stenosis on DSA, the % stenosis on MRA was 78%±22. vs 69%%±14 on DSA. MRA identified 96 of 99 arts seen on DSA (97%) Inter-rater reliability: DSA @ 50% stenotic threshold = 0.73 MRA @ 50% stenotic threshold = 0.83

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Thornton, J 1999	P,B, Consecutive Patients suspected of having secondary hypertension. Patients first had DSA followed by MRA within 1 month. All CE-MRA and DSA images reviewed by 3 masked observers. Consensus reached in each case. All pts had both studies	62 pts, 138 arts (age and sex unknown)	3D CE-MRA vs. DSA	88%	98%	MRA identified 129 of 138 arteries seen DSA (93%) MRA missed 9 accessory arteries seen on DSA Because the assessors had to reach consensus the inter-rater reliability cannot be assessed 21 stenoses detected by MRA, with 19 seen on DSA (2 false positives) 3 false negatives also reported

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Voiculescu 2001	P,B, Consecutive Pts with clinical suspicion of RAS were included DSA interpreted by 2 radiologists masked to each other Where radiologists disagreed on % of stenosis for DSA, a mean value was determined for final stenotic grade MRA interpreted by 2 other readers, masked to each other and to DSA results	36 pts, 77 arts 54yrs(24-79) 18♀, 28♂	CE-MRA and color Doppler vs. DSA	89% for all renal arts 96% in main renal arts	88% for all renal arts 86% for main renal arts	>60% stenosis is considered clinically significant CE-MRA was able to detect 90.9% of all renal arts, but only 55.5% of accessory arts No mention of how reader discordance was managed for CE-MRA Inter-rater reliability was not reported Compared to DSA, CE-MRA tended to overestimate degree of stenosis. With MRA, 6 main renal arteries showed stenosis, while DSA showed them as nonstenosed. In 2 of these 6 arteries, MRA showed >60% stenosis, while DSA indicated 45-50% stenosis

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Völk, M 2000	P,B, Consecutive Inclusion: Pts with clinical suspicion of RAS In 33 pts, DSA & MRA were performed within 24 hrs. In 7 pts, the studies were performed within 1 day to 4 months of each other 4 radiologists independently read MRA and DSA. Readers were unaware of DSA findings when reviewing MRA and vice versa. Nor were readers aware of pt. clinical history	40 pts, 99 arts 63yrs(25-81) 11♀, 29♂	3D CE-MRA Vs. DSA	93%[*]	83%[*]	In one pt, MRA was not diagnostic due to injector failure MRA vs. DSA for accessory arteries excluded from overall sens/spec calculations MRA detected 17 of 19 accessory arts confirmed by DSA Inter-rater reliability higher in MRA than DSA. 0.641 for DSA 0.494 for MRA

*Average value of all four radiologists for main renal artery findings

II. Aorto-Iliac Arteries

Author/ Year	Study Design	Study Population	Method	Sens @ >50% sten	Spec @ >50% sten	Comments
Dorenbeck, 2002	P, B Inclusion: All pts underwent bypass surgery for arterial occlusive disease Exclusion: Pts with general MRI contraindications DSA done within 3 days following bypass surgery, and MRA done within 5 days after DSA 4 radiologists reviewed MRAs independently and in a masked fashion Method for reviewing DSA not stated	15 pts Age/sex not stated	3D CE-MRA vs. DSA	100%	100%	No occlusions detected on either DSA or MRA MRA overestimated 5 stenoses. MRA called 4 of 5 vessels grade 2, while they were grade 1 on DSA In 1 MRA a vessel was labeled >75% stenosed, while on DSA it was 50-74% stenosed No overestimation was by more than 1 grade, and, in no case did it affect the diagnosis of significance Inter-rater reliability was 0.77

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Haney, TF 1997	P,B, Consecutive Inclusion criteria: 1)Pts referred for symptomatic aortoiliac disease; 2) Informed consent; 3) Could undergo MRA within 48 hrs of DSA Exclusion criteria: General MRI contraindications DSA read by 1 radiologist who was masked to MRA results MRA read by another radiologist who was masked to DSA results	39 pts, 323 arts 62yrs(34-81) 11♀, 28♂	3D CE-MRA vs. DSA .	93% renal 96% common iliac 93% external iliac 96% internal iliac	98% renal 100% common iliac 93% external iliac 94% internal iliac	No inter-rater reliability reported

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Meaney, 1999	P, B, consecutive Pts underwent elective DSA for lower extremity claudication MRAs reviewed by 2 independent radiologists in masked fashion If MRA readers disagreed on whether a vessel was patent or occluded, the 2 radiologists reached consensus DSAs reviewed by pairs of radiologists in consensus (masking to MRA results not stated) Time between MRA and DSA not stated Unclear if radiologists reading DSA were maskded to MRA results	20 pts 65 yrs (47-83) 12 ♂ 8♀ (26 pts invited, 5 refused, 1 had pacemaker)	3D CE-MRA vs DSA	The following sens info is based on comparison of CE-MRA to DSA for all segments reviewed. This included aorto-iliac and lower extremity vessels. (Sens data on only aorto-iliac vessels was not provided): sensitivity for diagnosing <50% from >50% stenosis = 81% sensitivity for diagnosing 100% stenosis (i.e. occlusion) = 94%	The following spec info is based on comparison of CE-MRA to DSA for all segments reviewed. This included aorto-iliac and lower extremity vessels. (Spec data on only aorto-iliac vessels was not provided): specificity for diagnosing <50% from >50% stenosis = 89% specificity for diagnosing 100% stenosis (i.e. occlusion) = 97%	

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Ruehm, 2000	P, B Inclusion: Pts referred for DSA to assess PVD (50) or graft patency (11), lack of contraindication to MRI, ability to do MRA within 72 hrs of DSA DSA and MRA interpreted by separate radiologists in a masked and independent fashion For evaluation purposes, arterial system divided into: distal aorta (DA), common iliac (CA) internal iliac (II) external iliac (EI), and leg arteries	61 pts 64yrs(41-83) 41 ♂ 20♀ 1769 arterial segments	3D CE-MRA vs. DSA	@ 50% stenosis DA = not reported CI = 93% EI = 94% II = 96% @ 100% stenosis DA = not reported CI = 100% EI = 100% II = 67%	@ 50% stenosis DA = not reported CI = 99% EI = 96% II = 93% @ 100% stenosis DA = not reported CI = 100% EI = 100% II = 99%	Poor quality MRA in 3% of arterial segments (58/1769) 39 arterial segments noted as >50% stenotic on MRA were graded as not significantly stenotic on DSA 15 arterial segments noted as >50% stenotic on DSA were graded as not significantly stenotic on DSA All aneurysms noted on DSA were also noted on MRA (n=9)

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Schoenberg 2002	P, B Inclusion criterion: All pts had DSA within 2 months before MRA MRA & DSA reviewed by 3 radiologists, each unaware of initial results of MRA or DSA	41 pts, 165 arts 56yrs(48-79) 12♀, 29♂ 76 renal 58 common iliac 31 external iliac	3D CE-MRA vs. DSA	Reader 1: 94% renal 80% common iliac 100% external iliac Reader 2: 97% renal 78% common iliac 78% external iliac Reader 3: 85% renal 85% common iliac 88% external iliac	Reader 1: 86% renal 90% common iliac 83% external iliac Reader 2: 85% renal 83% common iliac 92% external iliac Reader 3: 75% renal 89% common iliac 96% external iliac	Mean CE-MRA inter-rater reliability: Renal: 0.77 Common iliac: 0.77 External iliac: 0.49

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Torreggiani, 2002	P,B Inclusion criteria: 1) Pts with symptoms of aortoiliac occlusion, and 2) Pts unable to have perfemoral angiogram performed 28 pts presented. Of those, 9 were excluded (5 <u>could</u> have perfemoral angiogram, 1 had a pacemaker, and MRA not available for 3 pts) All pts had MRA within 48 hrs of DSA MRA reviewed independently by 2 radiologists masked to DSA results. If MRA reviewers disagreed, then MRA reviewed in consensus	19 pts 62yrs(45-77) 14 ♂ 5♀	3D CE-MRA vs DSA 5 pts received trans-lumbar DSA 14 pts received brachial DSA	aortic occlusions 88% iliac occlusions 100%	aortic occlusions 100% iliac occlusions 97%	Sens/spec information on aortic or iliac stenosis not given MRA image quality reported as excellent in 13 pts and good in 6 pts. Trans-lumbar and brachial DSA results combined results for sens/spec calculation

(See legend on next page)

#Arts = number of arteries
#Pts = number of patients
B = blinded
CA = catheter angiography
CE-MRA = contrast enhanced MRA
CI = common iliac
DSA = digital subtraction angiography
EI = external iliac
F-C = femorocrural
F-F = femorofemoral
FOV = field of view
F-P = femoralpopliteal
GD = gastroduodenal artery
HTN = hypertension
I-F = iliacofemoral
II – internal
I-P = iliacprofundal
MIP = maximum intensity projection
MRA = magnetic resonance angiography
N/A = not applicable
NB = not blinded
NR =not reported
P= prospective
PVD = peripheral vascular disease
R= retrospective
RAS = renal artery stenosis
RI = renal insufficiency
RVH = renovascular hypertension
Sens = sensitivity
SMA= superior mesenteric artery
Spec = specificity
Sten = stenosis